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# PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

| | |
|---|---|
| Date of mailing *(day/month/year)* | 16.04.2004 |
| Applicant's or agent's file reference: RLL-234WO | **IMPORTANT NOTIFICATION** |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/IB 03/00063 | 14.01.2003 | 15.01.2002 |

Applicant
RANBAXY LABORATORIES LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

| Name and mailing address of the international preliminary examining authority: | Authorized Officer |
|---|---|
| European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465 | Ladurner, Y<br>Tel. +49 89 2399-7913 |

PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
|---|---|---|
| RLL-234WO | | |
| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
| PCT/IB 03/00063 | 14.01.2003 | 15.01.2002 |
| International Patent Classification (IPC) or both national classification and IPC | | |
| A61K9/24 | | |
| Applicant | | |
| RANBAXY LABORATORIES LIMITED et al. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 14.08.2003 | 16.04.2004 |
| Name and mailing address of the international preliminary examining authority: | Authorized Officer |
| European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465 | Ganschow, S<br>Telephone No. +49 89 2399-7807 |

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB 03/00063

## I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

**Description, Pages**

1-12 as originally filed

**Claims, Numbers**

1-18 filed with telefax on 18.12.2003

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 18 |
| | No: | Claims | 1-17 |
| Inventive step (IS) | Yes: | Claims | |
| | No: | Claims | 1-18 |
| Industrial applicability (IA) | Yes: | Claims | 1-17 |
| | No: | Claims | |

2. Citations and explanations

**see separate sheet**

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. Claim 18 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim (Article 34(4)(a)(i) PCT).

**Re Item V**

**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

## 1. Documents

1.1. The present application relates to pharmaceutical compositions comprising a core, a seal coat on the core and an ACE inhibitor layer which is free of plasticizers and organic solvents.

1.2. Reference is made to the following documents:

D1: US 6 086 919 A (BAUER BRIGITTE ET AL) 11 July 2000 (2000-07-11)
D2: WO 01 51037 A (PHOENIX U S A INC LAB (US)) 19 July 2001 (2001-07-19)
D3: US 4 800 084 A (ZERBE HORST) 24 January 1989 (1989-01-24)

1.3. Reference is made to the passages cited in the International Search Report.

## 2. Method of treatment

2.1. For the assessment of the present claim 18 on the question whether it is industrially applicable, no unified criteria exist in the PCT Contracting States. The

patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

## 3. Novelty

3.1. D1 discloses a tablet containing ramipril in the coat and felodipine in the tablet core for preventing and treating hypertension. The coating is produced by spraying an ethanolic ramipril solution onto the tablet cores. Figure 3 refers to an intermediate layer between tablet layer containing the ramipril and another tablet layer containing dihydropyridine. However, this intermediate layer is not further characterized.

3.2. D2 teaches a core containing diltiazem. A polymer mixture with enalapril is sprayed onto the tablets. However, the coating always comprises polyethylene glycol as plasticizer.

3.3. None of the two cited documents discloses a pharmaceutical composition comprising a core coated with a seal coat and a layer of ACE inhibitor(s) which is free of plasticizers and organic solvents as defined in present claim 1.

3.4. However, document D3 refers to pharmaceutical preparations consisting of an inert core and multiple layers of different coatings. Figure 2 describes a core which is sealed by an insulating material which in turn is surrounded by a depository coating containing a pharmaceutically active agent, *e.g.*, captopril (column 2, line 64).

D3 also relates to the use of adhesive polymers, which dissolve in water, in order to guarantee the bonding of the depository coating and to prevent the destruction of this coating by mechanical stress.

Example 1 teaches a core made of sugar crystals that is tightly sealed by an insulating coating. Then, a depository coating comprising the active agent, lactose

and water is added to the insulated sugar balls while using an adhesive solution made of an adhesive polymer, which dissolve in water.

Hence, the depository coating is free of plasticizers and organic solvents.

3.4. Consequently, present claims 1 and 14 are not considered as novel pursuant to Art. 33(2) PCT. The same applies for dependent claims 2-13 and 15-17.

## 4. Inventive step

4.1. Since claims 1-17 are not novel, they do not fulfill the requirements of Art. 33(3) PCT (inventive step).

4.2. Document D1 already discloses the use of an ACE inhibitor in treating hypertension. Thus, nothing inventive can be seen in the use of a known composition comprising ACE inhibitors (see D3) for treating hypertension, congestive heart failure, left ventricular dysfunction and diabetic nephropathy.

Thus, present claim 18 is not considered as inventive pursuant to Art. 33(3) PCT.